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APOTECA

# 510(k) Summary K132011

## 1. Submitter Information

| | |
|---|---|
| Company Name: | AEA SRL |
| Company Address: | Via Fiume 16, Angeli di Rosora, Ancona, 60030, Italy |
| Company Phone: | 0039-0731-8161 |
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| Contact Person: | Michele Mengoni<br>Quality Assurance & Regulatory Affairs<br>Loccioni Humancare |
| Date Summary Prepared: | June 6, 2013 |

## 2. Device Identification

| | |
|---|---|
| Trade Name: | APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set |
| Common Name: | IV Fluid Transfer Set |
| Classification Name | Set, IV Fluid Transfer |
| Regulatory Class: | Class II |
| Regulation Number: | APOTECA® Drug Compounding Dosing Device: 21 CFR 880.5860<br>APOTECA® I.V. Transfer Set: 880.5440 |
| Product Code: | APOTECA® Drug Compounding Dosing Device: FMF<br>APOTECA® I.V. Transfer Set: LHI |
| Panel Identification | General Hospital |

## 3. Predicate Devices

| | |
|---|---|
| Trade Name: | Becton Dickinson Single Use Hypodermic Syringes |
| Manufacturer: | Becton, Dickinson and Company |
| 510(k) Number | K110771, K980987 |
| Trade Name: | Two-Fer™ Non-Coring Huber Point Needle |
| Manufacturer: | BAXA CORP. Englewood CO |
| 510(k) Number | K832347 |
| Trade Name: | TEVADAPTOR™ Spike Port Adaptor |
| Manufacturer: | Teva Medical Ltd. (Migada Plant) |
| 510(k) Number | K071741 |
| Trade Name: | TEVADAPTOR™ Connecting Set |
| Manufacturer: | Teva Medical Ltd. (Migada Plant) |
| 510(k) Number | K071741 |
| Trade Name: | PhaSeal® Secondary Set |
| Manufacturer: | Carmel Pharma AB. |
| 510(k) Number | K980381 |
| Trade Name: | Exacta-Mix 2400 Compounding System Administration Set |
| Manufacturer: | BAXA CORP. Englewood CO |
| 510(k) Number: | K002705 |

## 4. Device Description

The APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set is a system for preparation and administration of drugs intended for use with APOTECAchemo automatic compounding system.

**APOTECA® Drug Compounding Dosing Device**

The APOTECA® Drug Compounding Dosing Device is a single use piston syringe that consists of a syringe (3ml, 5ml, 10ml, 20ml, 50ml) with a luer lock connector bonded to a needle. The syringe consists of a plastic barrel with a graduated scale, a synthetic rubber stopper and a plastic plunger rod. The needle is a Huber point non-coring needle with 16G thin wall cannula (0.5" plus 0.5" inside the vented hub). The device is not manufactured with natural rubber latex. The device is designed to be handled manually or by automatic pharmacy compounding system for the preparation and admixture of drugs in healthcare establishments.
The change from the predicate devices is limited to its assembly configuration.
The APOTECA® Drug Compounding Dosing Device is provided sterile by EO sterilization method.

**APOTECA® I.V. Transfer Set**

The APOTECA® I.V. Transfer Set is a non-vented infusion set used as a connecting part between an IV bag and an external infusion line.
The device comprises of the following components:

- Non-vented spike
- Connecting tube
- Spike port adaptor with Twist-Off cap and safety membrane
- Luer lock adaptor with protective cap

The APOTECA® I.V. Transfer Set with a spike port adaptor is intended for the connection to the spike port of an IV infusion line. The short tubing enables the transfer of drug in a bag to a delivery set in the hospital ward.
The APOTECA® I.V. Transfer Set with a luer lock adaptor enables the connection of the set to the female luer port of an intravenous infusion line for direct drug transfer.
The APOTECA® I.V. Transfer Set with UV resistant connecting tube is indicated to be used with photosensitive drugs.
All devices are packaged sterile.

## 5. Intended Use

The APOTECA® Drug Compounding Dosing Device is indicated for use by pharmacists or other healthcare professionals for the preparation of chemotherapy drugs, for the transfer of drug from vials to IV bag for infusion. The drug transfer through the device can be performed manually or through an automatic pharmacy compounding system. The specific assembly configuration of the needle allows a robotic arm to manage the device and an automatic dosing device to transfer drug from a vial to a bag by applying pressure on the syringe plunger. The APOTECA® Drug Compounding Dosing Device is intended for use with APOTECAchemo automatic compounding system or for manual drug compounding.

The APOTECA® I.V. Transfer Set is a non-vented infusion set indicated to be used as a connecting part between the IV bag and an external IV line when the drug preparation is performed through an automatic pharmacy compounding system. The APOTECA® I.V. Transfer Set is intended for use with APOTECAchemo automatic compounding system.

## 6. Technological Characteristics Comparison to Predicate Device

A comparison of the technological characteristics of APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set and the predicate devices has been performed. The APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set is Substantially Equivalent to the predicate devices, given that:

- ✓ The APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set has the same intended use as the predicate device.
- ✓ The APOTECA® Drug Compounding Dosing Device syringe use an identical design and identical materials as the predicate device.
- ✓ The APOTECA® Drug Compounding Dosing Device needle use an identical design and identical materials as the predicate device.
- ✓ The APOTECA® Drug Compounding Dosing Device and the predicate devices meet the requirements for manual use and use with power-driven pumps as defined by ISO 7886-1 and ISO 7886-2 respectively.
- ✓ The APOTECA® Drug Compounding Dosing Device and the predicate devices are made of medical grade polypropylene compatible with cytotoxyc drugs.
- ✓ The APOTECA® Drug Compounding Dosing Device and the predicate device cannula are made of stainless steel AISI 304.
- ✓ The APOTECA® I.V. Transfer Set has the same components and materials as the predicate devices
- ✓ The APOTECA® I.V. Transfer Set has the same fitting connection to external standard IV bag as the predicate devices
- ✓ The APOTECA® I.V. Transfer Set has the same fitting connection to external standard IV line as the predicate devices
- ✓ The materials of the components of the APOTECA® Drug Compounding Dosing Device and I.V. Transfer and of the predicate devices comply with ISO 10993 as applicable to the intended use of the devices.
- ✓ The APOTECA® Drug Compounding Dosing Device and I.V. Transfer demonstrated equivalence performances to the predicate devices.

## 7. Performance Data

A product risk analysis was conducted according to ISO 14971:2007 and there were no new issues of safety and effectiveness. Bench tests were performed based on risk analysis to verify that the APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set can be handled by the APOTECAchemo automatic pharmacy compounding system for drug preparation.

Biocompatibility testing included the following:

| Performance Characteristic | Test | Acceptance Criteria |
|---|---|---|
| Hemolysis | ISO 10993-4:2002/A:2006 | Non-Toxic |
| Cytotoxicity | ISO 10993-5:1999 | Non-Toxic |
| EO Residual | ISO 10993-7:2008 | < Limit per device |
| Systemic Toxicity, Pyrogenicity | ISO 10993-11:2006 | Non-Toxic |
| Intracutaneous Reactivity | ISO 10993-10:2002 | Non-Irritant |

The additional tests referenced in the table below have been provided. AEA has included the additional airtight and leak proof requirements as both of these requirements are cited by the National Institute of Occupational Safety and Health (NIOSH) and the International Society Of Oncology Pharmacy Practioners (ISOPP)

| Performance Characteristic | Test | Result |
|---|---|---|
| Leak proof Connections | Fluorescein Test | No Leaks |
| Airtight Connections | $TiCl_4$ Test | No Visible Smoke |

## 8. Conformance of Standards

In terms of Physical Specification, Chemical Specification, Biological Specification, Packaging & Sterilization Specification, the submitted device conforms to applicable standards as described in the Conformance of Standards Summary Report

## 9. Additional Safety Information

Sterilization conditions have been validated in accordance with ISO 11135-1:2007 *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.* The device is sterilized to a SAL of $10^{-6}$. Bacterial Endotoxins test has been performed according to USP <85>.

## 10 Conclusion

The APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set has the same intended use as the predicate devices for the preparation and administration of parenteral drugs and has equivalent performance characteristics. The device submitted is therefore substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2014

AEA SRL
C/O Mr. Michele Mengoni
Quality Assurance & Regulatory Affairs
Via Fiume 16, Angeli di Rosora
Ancona, 60030
ITALY

Re: K132011
Trade/Device Name: APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, LHI
Dated: March 10, 2014
Received: March 13, 2014

Dear Mr. Mengoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K132011

Device Name: APOTECA® Drug Compounding Dosing Device and I.V. Transfer Set

**Indications For Use:**

**APOTECA® Drug Compounding Dosing**

The APOTECA® Drug Compounding Dosing Device is indicated for use by pharmacists or other healthcare professionals for the preparation of chemotherapy drugs, for the transfer of drug from vials to IV bag for infusion. The drug transfer through the device can be performed manually or through an automatic pharmacy compounding system. The specific assembly configuration of the needle allows a robotic arm to manage the device and an automatic dosing device to transfer drug from a vial to a bag by applying pressure on the syringe plunger. The APOTECA® Drug Compounding Dosing Device is intended for use with APOTECAchemo automatic compounding system or for manual drug compounding.

**APOTECA® I.V. Transfer Set**

The APOTECA® I.V. Transfer Set is a non-vented infusion set indicated to be used as a connecting part between the IV bag and an external IV line when the drug preparation is performed through an automatic pharmacy compounding system. The APOTECA® I.V. Transfer Set is intended for use with APOTECAchemo automatic compounding system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Richard C. Chapman
Date: 2014.03.21
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